



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

JUL 10 2000 4716 '00 JUL 11 PT 50

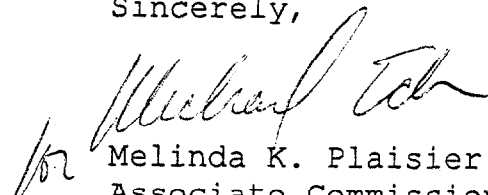
Mr. Peter Reinecke
Legislative Director
Office of Senator Tom Harkin
United States Senate
Washington, D.C. 20510-1502

Dear Mr. Reinecke:

Thank you for forwarding to the Food and Drug Administration (FDA) a copy of the "Ephedra Survey Results: 1995-1999," prepared for the American Herbal Products Association by Arthur Andersen LLP. As you requested, we have forwarded it to Joseph A. Levitt, Esq., Director, FDA Center for Food Safety and Applied Nutrition, and it will also be entered into the ephedra docket.

Thanks again for contacting us concerning this matter. If there is anything else we can assist you with, please let us know.

Sincerely,


Melinda K. Plaisier
Associate Commissioner
for Legislation

cc: Dockets Management Branch
(Docket 00N-1200)

00N-1200

RPT 2 /ANS

United States Senate

WASHINGTON, DC 20510-1502

COMMITTEES:
AGRICULTURE
APPROPRIATIONS
SMALL BUSINESS
LABOR AND HUMAN
RESOURCES

To: Melinda Plasser, FDA

Fr: P. Dr. Reincke

Date: June 5, 2000

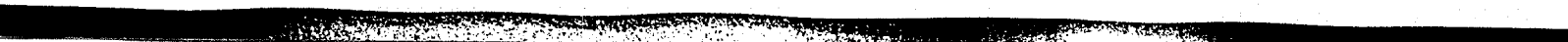
Attached is the survey of cythra
use we discussed. Please give it to
Joe and make sure it is included
in your analysis and record. Thanks.

No. 00-4027

Ephedra
Survey Results:
1995 – 1999

Prepared for:
The American Herbal Products
Association

Survey Administered &
Results Compiled by:
Arthur Andersen LLP
April 28, 2000



APPROACH & SCOPE

Arthur Andersen was engaged by the American Herbal Products Association ("AHPA") to administer and tabulate the results of a survey sent to companies that sold dietary supplements containing ephedrine alkaloids ("ephedra") in the years 1995 through 1999. The questionnaire, which was prepared by AHPA, was developed to capture information concerning the number of servings sold, the number of serious adverse events reported and other relevant information for products containing ephedra.

Arthur Andersen mailed the survey to 42 companies, whose names and addresses were supplied by AHPA. AHPA developed the target list from known companies in the industry that distribute dietary supplements containing ephedrine alkaloids and whose products were listed in the FDA's Initial Adverse Events Report as reported in a proposed rule published by FDA on June 4, 1997. Both members and non-members of AHPA were solicited.

Of the 42 companies solicited, Arthur Andersen received responses from 14 companies, an approximately 33% response rate.

The compiled results, presented on the following pages, are based on the responses of the 14 (unless otherwise noted) companies that sell, market and distribute products containing ephedrine alkaloids.

Compiled Survey Results

Based on the Answers of 14 Respondents

PART 1: GENERAL COMPANY INFORMATION

1. Number of years your company has been in business?

	Number of Respondents	% of Total Respondents
1 - 3 years	0	0%
4 - 6 years	1	7%
7 - 10 years	4	29%
> 10 years	9	64%

2. Annual sales volume for your company's entire product line.

Total Revenue (in Millions)	Number of Respondents	% of Total Respondents
\$50 and under	5	36%
\$51 - \$100	1	7%
Over \$100	8	57%

3. Annual sales volume for your company's products containing ephedrine alkaloids.

Revenue (in Millions)	Number of Respondents	% of Total Respondents
\$50 and under	10	71%
\$51 - \$100	2	14%
Over \$100	2	14%

4. Are you an AHPA member?

	Number of Respondents	% of Total Respondents
YES	8	57%
NO	6	43%

PART 2: EPHEDRA PRODUCT SALES INFORMATION

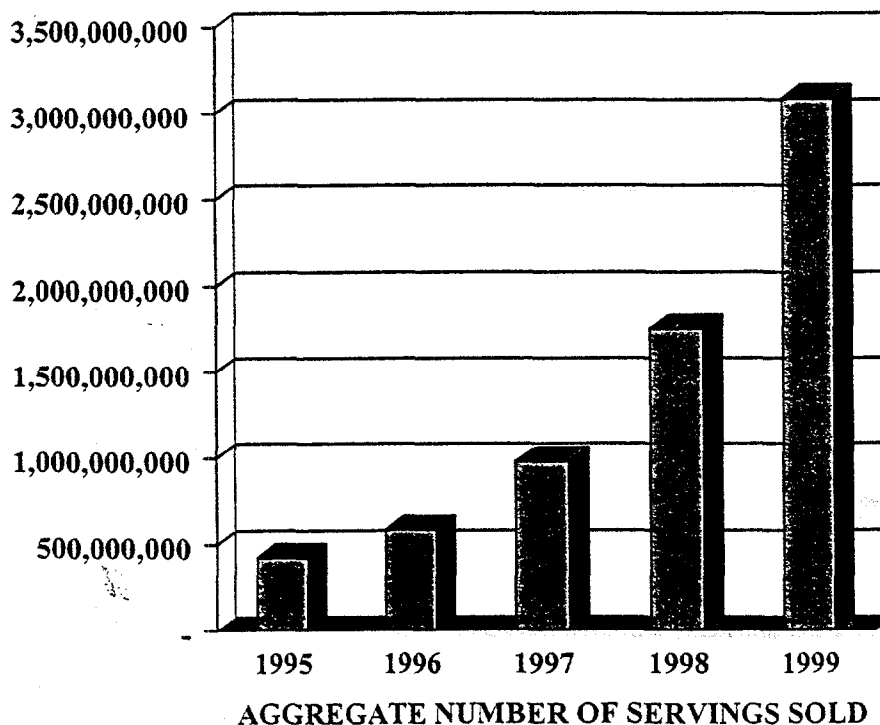
1. Number of products containing ephedrine alkaloids in your product line.

	Number of Respondents	% of Total Respondents
1 product	4	29%
2 - 3 products	2	14%
4 products or more	8	57%

2. For each year, list the "number of servings"* for all products sold containing ephedrine alkaloids.

[*A "serving" is the maximum amount to be consumed each use, per the directions on the label.]

	Aggregate Number of Servings Sold*	% Increase	
1995	424,965,043		* One respondent or 7% of the respondents did not answer this question. The aggregate number was calculated based on the responses of 13 respondents that answered this question.
1996	585,454,504	38%	
1997	976,466,984	67%	
1998	1,751,381,254	79%	
1999	3,086,041,072	76%	



3. What is the principal purpose(s) for which your product containing ephedrine alkaloids are marketed?

Product Purpose	Number of Respondents That Answered "Yes" (By Product Purpose)*	Aggregate Number of Products**
Energy	11	51
Asthma / Cold	4	6
Weight Loss	10	59
Increased Athletic Performance	6	10
Other	0	0

* Each respondent (total of 14) indicated for which purposes they market their products, either by answering "yes" or by providing the number of products for each product purpose category. Therefore, the maximum "Number of Respondents That Answered 'Yes' (By Product Purpose)" for each product category is 14.

** The "Aggregate Number of Products" only includes the responses of 12 participants. Two (2) respondents did not provide the number of products marketed for each purpose category; they only answered with a "yes" or "no" response.

4. For each product manufactured, what is the maximum amount, in milligrams of ephedrine alkaloids, recommended for each serving?

Recommended Serving Size	Number of Respondents That Answered "Yes" (By Serving Size)*	Aggregate Number of Products**
Less than 10 mg:	4	28
10 - 15 mg:	3	22
16 - 25 mg:	11	33
26 mg or more:	1	1

* Each respondent (total of 14) indicated which serving size categories are recommended for their products, either by answering "yes" or by providing the number of products for each serving size category. Therefore, the maximum "Number of Respondents That Answered 'Yes' (By Serving Size)" for each serving size category is 14.

** The "Aggregate Number of Products" only includes the responses of 12 participants. Two (2) respondents did not provide the number of products for each serving size category; they only answered with a "yes" or "no" response.

5. For each product manufactured, what is the maximum amount, in milligrams of ephedrine alkaloids, recommended to be consumed in a 24-hour period?

Maximum Dosage in a 24-Hour Period	Number of Respondents That Answered "Yes" (By Maximum Dosage)*	Aggregate Number of Products**
25 - 50 mg	5	63
51 - 100 mg	11	60
More than 100 mg	0	0

* Each respondent (total of 14) indicated which maximum dosage categories are recommended for their products, either by answering "yes" or by providing the number of products for each serving size category. Therefore, the maximum "Number of Respondents That Answered 'Yes' (By Maximum Dosage)" for each maximum dosage category is 14.

** The "Aggregate Number of Products" only includes the responses of 12 participants. Two (2) respondents did not provide the number of products for each maximum dosage category; they only answered with a "yes" or "no" response.

PART 3: MANUFACTURING OF EPHEDRA PRODUCTS

1. Do you follow or do you require your manufacturer to follow GMPs?

	Number of Respondents	% of Total Respondents
YES	14	100%
NO	0	0%

2. If "NO" to #1, do you currently have plans to develop and implement GMPs?

None of the survey respondents answered "NO" to Question 1. Therefore, this question is not applicable.

3. Do you put lot numbers on each of your products to be able to identify the specific batch or lot manufactured?

	Number of Respondents	% of Total Respondents
YES	14	100%
NO	0	0%

4. If "NO" to #3, do you plan to implement a lot numbering system to be able to identify the specific batch or lot manufactured?

None of the survey respondents answered "NO" to Question 3. Therefore, this question is not applicable.

5. Do you or outside laboratories test each lot manufactured for the amount of ephedrine alkaloids in the finished product?

	Number of Respondents	% of Total Respondents
YES	13	93%
NO	1	7%

6. If "YES" to #5, please briefly describe the method to test the finished product.

The following methods were listed as the most common forms of testing the finished products.*

- Six respondents use a form of High Performance Liquid Chromatography (HPLC) or Inductively Coupled Plasma (ICP).
- One respondent uses the CE method.
- Four respondents stated that they use an external source such as an external laboratory or the manufacturer to test their products.
- Two respondents use Inductively Coupled Plasma (ICP).
- One respondent uses an in-house test laboratory.
- One respondent uses the Capillary Electrophoresis method.
- One respondent does not test the finished product.

* Two (2) respondents listed more than one method.

7. Do you include any synthetic ephedrine (i.e. ephedrine HCl) as an ingredient in any of your products?

	Number of Respondents	% of Total Respondents
YES	0	0%
NO	14	100%



PART 4: LABELING OF EPHEDRA PRODUCTS

1. Do you include a cautionary statement on products containing ephedrine alkaloids?

	Number of Respondents	% of Total Respondents	
YES*	14	100%	* One respondent stated that they use a cautionary statement on SOME, but NOT ALL products. This response was included as a "Yes" response.
NO	0	0%	

If "YES" to #1, do you use a cautionary statement substantially similar to the following statement?

Not for use by anyone under the age of 18. Do not use this product if you are pregnant or nursing. Consult a health care professional before using this product if you have heart disease, thyroid disease, diabetes, high blood pressure, psychiatric condition, difficulty in urinating, prostate enlargement, or seizure disorder, if you are using a monoamine oxidase inhibitor (MAOI) or any other prescription drug, or you are using an over-the-counter drug containing ephedrine, pseudo-ephedrine or phenylpropanolamine (ingredients found in certain allergy, asthma, cough/cold and weight control products).

Exceeding recommended serving will not improve results and may cause serious adverse health effects.

Discontinue use and call a health care professional immediately if you experience rapid heartbeat, dizziness, severe headache, shortness of breath, or other similar symptoms

	Number of Respondents	% of Total Respondents
YES	12	86%
NO	0	0%
Did Not Answer	2	14%

2. Do you state on your label that the product is not recommended for consumption by or sale to minors (under 18 years of age)?

	Number of Respondents	% of Total Respondents
YES	13	93%
NO	1	7%

3. Do you state on the label the amount (in milligrams) of ephedrine alkaloids contained in the product?

	Number of Respondents	% of Total Respondents
YES	14	100%
NO	0	0%

4. If your product(s) contains xanthine alkaloids (i.e. caffeine), do you state on the label the amount, in milligrams, of xanthine alkaloids contained in the product?

	Number of Respondents	% of Total Respondents
YES	12	86%
NO	1	7%
Not Applicable	1	7%

5. In listing Ephedra on your label, which term do you use?

	Number of Respondents	% of Total Respondents
Ephedra or ma Huang	14	100%
Other	0	0%

PART 5: ILLNESS AND INJURY

For purposes of this section, a "serious adverse event" is defined as any report of a person suffering a heart attack, stroke, seizure, death or other injury that resulted in hospitalization or treatment by a physician.

1. Do you have a system for collecting reports of "serious adverse events" allegedly related to the consumption of your products containing ephedrine alkaloids?

	Number of Respondents	% of Total Respondents
YES	14	100%
NO	0	0%

2. By year, state the number of "serious adverse events" that have been reported to your company, which were allegedly related to the consumption of your products containing ephedrine alkaloids.

	Aggregate Number of Reported "Serious Adverse Events"	Number of Reported Events per Million Servings Sold*
1995	5	0.01177
1996	3	0.00512
1997	18	0.01843
1998	15	0.00856
1999	25	0.00810

* AA calculated "Number of Reported Events per Million Serving Sold". Number of Reported Events per Million Serving Sold = Aggregate Number of Reported Serious Adverse Events in Part 5, Question 2 ÷ Aggregate Number of Servings Sold in Part 2, Question 2.

